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Giannini, Andrea

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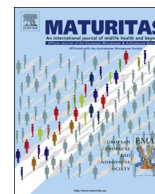
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Current management of pelvic organ prolapse in aging women: EMAS clinical guide

Andrea Giannini^{a,1}, Eleonora Russo^{a,1}, Antonio Cano^b, Peter Chedraui^c, Dimitrios G. Goulis^d, Irene Lambrinoudaki^e, Patrice Lopes^{f,g}, Gita Mishra^h, Alfred Mueckⁱ, Margaret Rees^j, Levent M. Senturk^k, John C. Stevenson^l, Petra Stute^m, Pauliina Tuomikoskiⁿ, Tommaso Simoncini^{a,*}

^a Department of Clinical and Experimental Medicine, University of Pisa, Via Roma, 67, 56100, Pisa, Italy

^b Department of Pediatrics, Obstetrics and Gynecology, University of Valencia and INCLIVA, Valencia, Spain

^c Institute of Biomedicine, Research Area for Women's Health, Facultad de Ciencias Médicas, Universidad Católica de Santiago de Guayaquil, Guayaquil, Ecuador

^d Unit of Reproductive Endocrinology, First Department of Obstetrics and Gynecology, Medical School, Aristotle University of Thessaloniki, Greece

^e Second Department of Obstetrics and Gynecology, National and Kapodistrian University of Athens, Greece

^f Nantes, France Polyclinique de l'Atlantique Saint Herblain, F 44819 St Herblain, France

^g Université de Nantes, F 44093 Nantes Cedex, France

^h School of Public Health, Faculty of Medicine, University of Queensland, Brisbane 4006, Australia

ⁱ University Women's Hospital of Tuebingen, Calwer Street 7, 72076 Tuebingen, Germany

^j Women's Centre, John Radcliffe Hospital, Oxford OX3 9DU, UK

^k Istanbul University Cerrahpasa School of Medicine, Dept. of Obstetrics and Gynecology, Division of Reproductive Endocrinology, IVF Unit, Istanbul, Turkey

^l National Heart and Lung Institute, Imperial College London, Royal Brompton Hospital, London SW3 6NP, UK

^m Department of Obstetrics and Gynecology, University Women's Hospital, Bern, Switzerland

ⁿ Helsinki University and Helsinki University Hospital, Eira Hospital, Helsinki, Finland

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ABSTRACT

Management of pelvic organ prolapse (POP) is a common and challenging task. Nowadays older women are more active than they were in the past, and the development of POP disrupts quality of life and impairs social and personal activities. The menopausal transition is a time of vulnerability, during which many women start experiencing symptoms and signs of POP. The role of hormonal changes or of hormonal therapies in influencing the development or progression of POP has been explored extensively. The management of POP requires considerable clinical skills. Correct diagnosis and characterization of the prolapse and an identification of the individual woman's most bothersome symptoms are the hallmark of appropriate initial management. Therapy is multimodal and often multidisciplinary, and requires a competence in pelvic medicine and surgery. The integration of hormonal, non-hormonal and surgical strategies is important and needs to be adjusted to changing circumstances on an individualized basis. When surgery is required, optimal management requires clinicians who are familiar with the advantages and disadvantages of all the available strategies and who are able to use these strategies in a tailored manner. Complex cases should be sent to specialist referral centers. Management of POP should be integrated into the practice of healthcare professionals dealing in menopause.

1. Introduction

1.1. Definitions, epidemiology and clinical picture

Pelvic floor disorders include pelvic organ prolapse (POP), urinary incontinence (UI), fecal incontinence, pelvic pain and sexual dysfunction.

POP is clinically defined as “the descent of one or more of the anterior

vaginal wall, posterior vaginal wall, the uterus (cervix) or the apex of the vagina (vaginal vault or cuff scar after hysterectomy)” [1]. The incidence and prevalence of POP have not been systematically investigated. While it is estimated that nearly 50% of women will develop some form of prolapse, only 10–20% of all women seek medical assistance [2]. The prevalence of POP increases with age, with a peak incidence in women aged 60–69 [3]. POP can be identified in up to 50% of women upon vaginal inspection,

* Corresponding author at: Department of Clinical and Experimental Medicine, Division of Obstetrics and Gynecology, University of Pisa, Via Roma, 67, 56126, Pisa, Italy.

E-mail address: tommaso.simoncini@med.unipi.it (T. Simoncini).

¹ These two authors contributed equally to the paper.

but if POP is defined by the presence of clinically relevant symptoms, its prevalence in the general population may range between 3% and 6%, since mild or moderate POP is frequently asymptomatic [4].

The etiology of POP is multifactorial. Risk factors include pregnancy, childbirth, obesity, congenital or acquired connective tissue abnormalities, chronic constipation, family history of POP, denervation or weakness of the pelvic floor, the menopause and aging [2,5–9].

POP-related symptoms may vary based on the anatomical defect(s) or in relation to the degree of bladder, bowel and sexual dysfunction [1]. While many symptoms attributed to POP have a weak to moderate correlation with a defect in pelvic organ support, moderate to advanced POP is characterized by report of a vaginal bulge. The anatomic threshold for symptomatic prolapse appears to be the hymen. Medical attention is not frequently sought for early-stage POP, although it is often identified in young and active women, who complain of subjective impairment of their quality of life, particularly concerning their sexual or work life, and physical activity [10].

Bladder and urethral function are frequently affected by loss of support of the anterior vaginal wall and apex. Symptoms of stress urinary incontinence (SUI) often coexist with stage I or II anterior prolapse (as defined below). However, as the anterior prolapse worsens, most women see improvements in SUI and in fact may experience progressive voiding impairment due to bladder outlet obstruction. In this circumstance, women often report symptoms such as voiding hesitancy, prolonged or intermittent flow, the need to push the POP up to aid voiding and the sensation of incomplete bladder emptying. Women with POP also have an increased risk of overactive bladder symptoms, such as urgency, urge urinary incontinence, frequency and nocturia [11].

Defecatory symptoms are common in women with POP and may occur with any defect of the posterior compartment, including rectocele, enterocele, sigmoidocele, internal rectal prolapse or full mucosal rectal prolapse. Constipation, incomplete evacuation and obstructed defecation are common complaints. Straining and the need to exert digital manipulation to complete evacuation are clinical hallmarks of obstructed defecation syndrome.

The evaluation of a patient with vaginal prolapse requires complete assessments of the anatomical defect, of the full spectrum of pelvic floor symptoms and of how these symptoms affect quality of life.

The use of a standardized system to describe POP is a key component of treatment. The Pelvic Organ Prolapse Quantification (POP-Q) system is internationally regarded as the standard for this purpose. It provides a reproducible description of the support of the anterior, posterior and apical vaginal segments using precise measurements to a fixed reference point, the hymen, and established criteria for staging the various levels of pelvic organ support from good support (POP-Q stage 0 or I) to almost complete lack of support (POP-Q stage IV). For the further qualitative assessment of symptoms, a number of questionnaires and instruments for condition-specific health-related quality of life (HRQOL) are available and validated in different languages [12–15].

1.2. Age- and menopause-related modifications to the pelvic floor

Menopause is reckoned to be a key event associated with the emergence or a worsening of POP. Symptoms and severity increase significantly across the menopausal transition [7]. Despite this, it is difficult to differentiate the specific contribution of estrogen withdrawal from that of the aging process *per se*. Pelvic organs, and their muscular and connective tissue supports, are estrogen-responsive.

The sensitivity of the urogenital tissues to sex steroid hormones has been posited as an explanation for the frequent report of symptoms in the lower urinary tract at the menopause. A panel of experts recently incorporated this increased frequency of urinary tract symptoms into a unifying concept called the genitourinary syndrome of menopause (GSM) [16]. GSM is defined as a collection of symptoms and signs associated with a decrease in estrogen and other sex steroids; these symptoms and signs include changes in the labia majora and minora,

clitoris, vestibule/introitus, vagina, urethra and bladder. The syndrome may include but is not limited to: genital symptoms such as dryness, burning and irritation; sexual symptoms such as lack of lubrication, discomfort or pain, and impaired sexual function; and urinary symptoms such as urgency, dysuria and recurrent urinary tract infections. Women may present with some or all of the signs and symptoms, which must be bothersome and not attributable to another diagnosis [16]. While the creation of a new medical entity has been broadly debated and criticized, it highlights how menopause does not affect solely vaginal tissues.

1.3. Impact of estrogen therapy on pelvic floor disorders

Withdrawal of estrogens during the menopausal transition results in changes in the vagina and external genitalia that are collectively known as vulvovaginal atrophy (VVA). Menopause is also associated with significant changes in the low urinary tract and the pelvic floor. The urethra and surrounding tissues, the bladder muscle and mucosa, and the pelvic floor muscles all express estrogen receptors and become to some extent dysfunctional in the absence of estrogens. Nearly 50% of postmenopausal women have clinical symptoms related to VVA [17]. Any use of estrogens, orally, transdermally or vaginally, improves VVA. While vaginal estrogen therapy provides symptomatic relief for urogenital atrophy, there is no evidence that it is beneficial in preventing or limiting the progression of POP. Women are wary of estrogen treatment: 41% of women have long-term safety concerns and 30% are apprehensive about breast cancer. Nine percent of menopausal women receiving a vaginal estrogen prescription never take the medication, and those who do typically discontinue therapy after just 3 months. This reluctance of women to use vaginal estrogens and physician disinclination to recommend such therapy suggest either that such preparations are not very effective or that their utility is underappreciated [18].

A Cochrane systematic review published in 2010 regarding the role of estrogens in preventing or treating female POP found scarce data in this regard [19]. The only information from randomized trials comes from the pooled data from trials of raloxifene carried out in postmenopausal women aimed at preventing or treating osteoporosis; these studies reported a decreased rate of prolapse surgery in women over 60 years of age treated with raloxifene [19]. Studies evaluating the effect of local estrogens versus placebo or no treatment in women with POP have mainly assessed VVA symptoms and signs rather than POP symptoms, and thus provide little evidence on the clinical utility of such treatment in the prevention or treatment of POP. A recent analysis from the Women's Health Initiative trial suggested that bilateral salpingo-oophorectomy at the time of hysterectomy is not associated with increased risk of cystocele or rectocele. Moreover, bilateral salpingo-oophorectomy and no subsequent hormone therapy may have a protective effect against cystocele or rectocele, thus confirming the evidence regarding estrogen therapy's limited effectiveness in the prevention and treatment of POP [20].

1.4. Perioperative use of estrogens in POP surgery

The evidence regarding the use of vaginal estrogen before prolapse surgery is inconsistent. It is uncertain whether preoperative vaginal estrogen is beneficial. The use of vaginal estrogens improves the vaginal maturation index at the time of surgery and increases vaginal epithelial thickness, but this does not translate into increased vaginal sub-epithelial/muscularis thickness [18,21] and thus any possible surgical advantages are to be proved. One study found that the use of vaginal estrogens preoperatively decreases the frequency of bacteriuria after surgery, but no difference in the incidence of symptomatic cystitis [22]; however, the study design does not allow for a comparison of the effect of vaginal estrogens on other urinary complaints or on the integrity of prolapse repair or wound healing [22].

Three studies have evaluated the use of vaginal estrogens after

pelvic reconstructive surgery, with a total of 297 participants; overall, the quality of the evidence was poor. There were net benefits with estrogen application after surgery, with decreased prevalence or severity of urinary frequency and urgency, and less common granulation tissue compared with placebo vaginal ring and other objective signs of atrophy. The impact of local estrogen on prolapse recurrence, nocturia, urgency urinary incontinence, urodynamic measures, or postoperative urinary tract infection was uncertain. No studies were powered to determine the effect of postoperative vaginal estrogen on surgical complications such as mesh erosion. There were no significant adverse events attributable to vaginal estrogen [23–25].

In conclusion, although vaginal estrogen is safe, there is limited evidence that it can aid prolapse surgery by decreasing the likelihood of early postoperative urinary tract infection and surgery-related symptoms.

2. Contemporary treatment of pop

Treatment of POP should be reserved for symptomatic women and tailored to the individual woman's symptoms; treatment of an asymptomatic prolapse with a surgical intervention in particular should be discouraged. Treatment of POP includes conservative management (lifestyle modifications and physical therapies), surgery or pessaries. The choice of approach must take into account the woman's preference, as well as her ability to comply with conservative therapy and to tolerate surgery.

2.1. Conservative management

• Lifestyle intervention and physical therapies

The first-line intervention for POP is conservative management, which is usually a valid option for women with a mild degree of prolapse and mild symptoms [26]. Lifestyle modifications include: dietary changes, weight loss, reduction of activities that strain the pelvic floor, treatment of constipation and cessation of smoking. While these interventions seem to mitigate POP symptoms, their effect on POP progression is still not established.

Physical therapies improve POP symptoms and help restore pelvic floor function. These interventions include physical activity, cognitive behavioral therapy, bladder training, bowel habit training, biofeedback and electrical muscle stimulation [27]. Pelvic floor muscle training involves the contraction of the pelvic floor muscles to improve strength, endurance and timing of contractions in order to better support the pelvic organs. Several meta-analyses show that women with symptomatic mild POP treated with pelvic floor muscle training undergo significant improvement of prolapse symptoms and POP severity [28–30]. No data are available on the efficacy of pelvic floor muscle training in aiding POP surgery, although most experts consider it useful [30,31].

2.2. CO₂ Laser and Er:YAG laser (VEL)

Laser therapy has gained attention as an effective treatment for VVA and is currently under scrutiny for its potential to improve urinary continence and possibly pelvic support. Micro-ablative fractional CO₂ laser and the non-ablative vaginal Er:YAG laser (VEL) induce morphological changes in vaginal tissues through the generation of new collagen. The largest body of data regarding laser therapy is on the treatment of VVA [32,33]. Given its effects on collagen and pelvic floor tissue, laser treatment shows promise as a non-surgical method for treating mild POP and SUI [34–38]. At present, the data to support the use of lasers for SUI and POP is limited. Randomized studies are needed to compare different laser technologies, and to compare the effect of laser treatment with other therapies, as well as to assess the duration of the therapeutic effects and the safety of repeated applications [39].

2.3. Reconstructive surgery

Women with symptomatic prolapse who have failed conservative management are candidates for reconstructive surgery. There is no indication for the repair of asymptomatic POP as an isolated procedure. It is important to identify symptoms that are attributable to each specific anatomical compartment, since this aids surgical decision-making. Several factors affect surgical planning, primarily the combination or complexity of anatomical defects and the individual's risks of surgical complications. Isolated repair of anterior, posterior or apical vaginal wall prolapse is typically performed transvaginally. Abdominal surgery is more effective and safer for the management of advanced or multi-compartmental POP.

• Anterior compartment surgery

Anterior vaginal wall POP may be due to central or lateral defects. Central defects result from vertical defects in the endopelvic fascia. Lateral defects result from detachment of the lateral vaginal wall from the arcus tendineus fascia pelvis.

Anterior colporrhaphy is the procedure most commonly performed for the management of anterior prolapse, independently from the location of the fascial defect. Objective success rates range from 80% to 100% when anterior colporrhaphy is used to treat isolated cystocele [40]. Anterior vaginal wall defects are often associated with descent of the apex. Concomitant apical support increases long-term success when compared with isolated anterior compartment repair [41].

Paravaginal repair (vaginal paravaginal or abdominal paravaginal) for lateral defects is rarely performed and there are no randomized trials to evaluate its outcomes.

Although the use of permanent meshes provides successful anatomical improvement of the anterior compartment and reduces the subjective sensation of bulge when compared with anterior colporrhaphy, prosthetic surgery is associated with serious complications, particularly mesh exposures (11.3%), leading to a higher rate of reoperation (7%) relative to native tissue repair [42,43]. Hence, the use of polypropylene meshes as a first-line intervention for anterior compartment prolapse is not recommended [43]. The use of absorbable meshes or biological grafts in anterior compartment surgery may increase the success rate of native tissue repair of anterior compartment defects, but this has not been thoroughly investigated and biocompatible materials may be expensive [40].

• Posterior compartment surgery

Posterior vaginal wall prolapse can include high defects (vaginal vault prolapse and enterocele) as well as middle and low rectoceles. The repair of posterior vaginal prolapse can be addressed with vaginal, transanal or abdominal approaches. There is an ongoing debate regarding the best approach to treat the different prolapses of the posterior compartment, with differing views between gynecologists and proctologists. It is now clear that rectocele is one of the many forms of rectal prolapse, and when rectocele is associated with defecatory symptoms a thorough proctological assessment should be undertaken preoperatively. Surgical strategies to address posterior vaginal wall prolapse should additionally aim to restore bowel function. Low rectoceles in the absence of defecatory symptoms, which often present with an isolated bulging sensation, can be effectively treated with transvaginal plication surgery.

Transvaginal repair of low rectocele is a good option in symptomatic (bulge) middle or low posterior vaginal wall prolapse. Traditional posterior colporrhaphy with or without levator ani plication represents the most common approach. Success rates range from 76% to 100% [44]. Muscle plication should be avoided in sexually active women because it frequently causes dyspareunia.

There is no indication for the use of biological grafts or

polypropylene meshes as first-line strategies, as there is no evidence of improved outcomes and there may be complications [2].

Transanal surgery, comprising plication strategies, is effective to treat rectal prolapse or intussusception with defecatory dysfunction. However, surgeons need to take into account anal sphincter function, as these procedures may be associated with *de novo* gas or fecal incontinence.

• Apical compartment surgery

Apical prolapse (uterus or vaginal vault) is often present in women with prolapse; when it extends beyond the hymen, it is very bothersome. Effective support of the apex is an essential element of any surgical treatment for advanced POP [45]. Nonetheless, the management of apical prolapse remains challenging. An abdominal approach with prosthetic sacral colpopexy is considered the gold standard for the treatment of apical defects. Abdominal sacral colpopexy is associated with lower risks of recurrence (both awareness of prolapse on the part of the patient, and prolapse evident upon examination), repeat prolapse surgery, post-operative SUI and dyspareunia when compared with vaginal procedures [46].

2.3.1. Vaginal approach

A vaginal approach is a reasonable alternative to abdominal techniques for women who cannot tolerate general anesthesia, those without major risk factors for prolapse recurrence, and when concomitant vaginal surgery is required (for example to restore continence).

Vaginal surgical approaches for apical repair include sacrospinous and uterosacral ligament suspension [47]. Vaginal hysterectomy with uterosacral ligament suspension is the technique most commonly performed for apical prolapse repair. When the apical defect coexists with anterior or posterior defects, anterior colporrhaphy or posterior colporrhaphy can be performed at the same time. Removal of the uterus helps to achieve apical suspension when a vaginal approach is used, as it is technically simpler and more effective to attach the vaginal vault to the uterosacral or sacrospinous ligaments than the cervix or the isthmus. However, hysterectomy is not necessarily required for POP reconstructive surgery. The majority of women are concerned about the risks of hysterectomy and would prefer uterine conservation if it is technically feasible, in order to maintain future fertility, or due to the belief that cervix removal may affect sexual function, or, often, due to the psychological identification of this organ with a sense of gender and personal identity [48].

For women with mild uterine prolapse, the Manchester procedure and sacrospinous hysteropexy are feasible and safe [49]. The Manchester procedure is a good option to correct apical prolapse due to cervical elongation in premenopausal women, since it preserves fertility. Sacrospinous hysteropexy seems as effective as vaginal hysterectomy, but reduces operating time, blood loss and recovery time [50]. However, long-term data are limited and the need for subsequent hysterectomy is unknown.

Nevertheless, women with advanced apical prolapse have a higher risk of recurrence when treated transvaginally, particularly if uterine preservation is desired; therefore, abdominal procedures are best in such circumstances.

2.3.2. Abdominal approach

Abdominal sacral colpopexy is the gold standard for the management of advanced apical defects [46]. Although the majority of outcome studies regarding abdominal sacral colpopexy used an open technique, laparoscopic and robot-assisted approaches are now more commonly performed, since they combine efficacy with minimization of surgical invasiveness. Data suggest that the conventional laparoscopic and robot-assisted laparoscopic approaches result in a shorter hospital stay, faster recovery time, a significant decrease in blood loss,

and less postoperative pain than laparotomy, but have comparable short-term efficacy, ranging between 85% and 100% [51]. Robotic surgical systems have been developed with the goal of facilitating technically difficult procedures by improving the surgeon's vision, dexterity and ergonomics. The technical advantages conferred by the robotic platforms are particularly useful in pelvic floor reconstructive surgery, and the introduction of new devices is likely to have a profound impact in this field. Although further studies are necessary to clarify the possible advantages of robotic versus laparoscopic abdominal sacral colpopexy, the data so far suggest that the laparoscopic route may be more cost-effective and confer more benefit to women [51–54]. However, the studies suffer from a lack of standardization of robotic procedures and sample sizes are small. Larger datasets will become available as robotic surgery becomes more widely disseminated, which will allow firmer conclusions to be drawn.

Lateral apical mesh suspension to the abdominal wall is a recently developed surgical approach that effectively treats advanced apical prolapse while avoiding pre-sacral dissection and the related complications. Lateral apical mesh suspension is a safe and simpler technique than abdominal sacral colpopexy and it seems to be highly effective [55–59]. However, a trial comparing lateral apical mesh suspension with abdominal sacral colpopexy for the treatment of apical prolapse is currently not available.

2.3.3. Transvaginal prosthetic surgery

Transvaginal mesh kits are highly effective in restoring apical prolapse [46]. However, in July 2011, the US Food and Drug Administration (FDA) classified transvaginal meshes used for prolapse as high-risk devices, and they lost popularity. The main concern raised by the FDA is related to vaginal pain, dyspareunia and mesh erosions and infections, which are not rare in women treated with these devices. Many transvaginal mesh kits were removed from the market following the FDA alert. Newer, lighter-weight transvaginal meshes are now available; however, to date, no data show a lower rate of complications with these newer materials [60].

Nonetheless, there is a select group of women who are good candidates for the use of transvaginal meshes in the hands of specialist surgeons trained in SUI and pelvic floor reconstructive surgery, including the use of specific transvaginal synthetic mesh prolapse kits and the treatment of potential mesh-related complications [60–69]. It is essential that the surgeons provide information about the risks and benefits of transvaginal mesh procedures so that women can review all the treatment options available to them and participate actively in decision-making.

Currently, transvaginal meshes should be used only in research contexts [70], in complex cases or to treat recurrent prolapse, when other strategies are not feasible or are clearly less effective [71].

The relatively high rate of mesh-related complications associated with their transvaginal use has not been observed with abdominal approaches using the same synthetic meshes. Abdominal procedures are associated with erosion (albeit rarely, in 0–8% of cases), which are mostly observed when total hysterectomy is performed with immediate attachment of a mesh to the sutured vaginal vault [72]. This suggests that bacterial mesh contamination at the time of vaginal introduction is the main reason for the higher rate of mesh-related complications seen with transvaginal kits.

2.4. Obliterative surgery and pessaries

The choice of reconstructive procedures in preference to obliterative procedures depends upon the clinician's medical skills and the woman's sexual function.

Total colpocleisis or LeFort partial colpocleisis corrects POP by closing off the vaginal canal either in part or entirely [73]. Obliterative procedures are reserved for elderly, frail women with advanced POP, who cannot have extensive surgery and do not wish to conserve sexual

function. Colpocleisis provides good relief of pelvic floor symptoms and has low rates of morbidity [47]. The anatomical success rate of these procedures is 90%.

Vaginal pessaries are a safe and effective option for women with POP as an alternative to surgery for symptomatic elderly women, or for women who wish to become pregnant, or for those who prefer a non-surgical treatment. Pessaries are also commonly used in women requiring symptomatic relief while awaiting surgery. Pessaries are silicone devices that are inserted into the vagina to keep the prolapsed organs in their normal position and hence relieve symptoms. Two main types of vaginal pessaries are used: support and space-filling pessaries [27]. There is evidence of their effectiveness from several randomized controlled trials and observational studies. Complications are usually minor, vaginal discharge being the most common [27,74,75]. There is no consensus on the use of different types of pessaries for specific types of prolapse, nor on the pattern of replacement, the treatment of complications and appropriate length of follow-up [76].

3. Conclusions

The burden of POP on women's health is rising as life expectancy is increasing. POP can be devastating, disrupting social, sexual and daily activities. Healthcare professionals in the field of menopause are in a key position to identify the problem, to characterize it, and either to manage it themselves or to refer women appropriately. POP management is challenging and requires advanced skills, particularly when surgery is required. POP should not be ignored and women should be informed of the available treatments and participate actively with their healthcare professional in making management decisions. Clinical services should be able to offer up-to-date non-surgical and surgical options in order to satisfy treatment demands for this growing problem and to help women enjoy their later years.

Contributors

Andrea Giannini, Eleonora Russo and Tommaso Simoncini prepared the initial draft, which was circulated to all other named authors – EMAS board members – for comments and approval; production was coordinated by Irene Lambrinoudaki and Margaret Rees.

Conflict of interest

1. Andrea Giannini, none declared.
2. Eleonora Russo, none declared.
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